

Remarks

Claims 1-75 are pending in the application, and are subject to a restriction requirement.

Response to Restriction Requirement

Applicants elect, with traverse, Group I (claims 1-9 and 64-69), drawn to synthetic peptides, for the reasons outlined below.

The Examiner has also requested that, with the election of any group, a further species election must be made from the peptide groups XBBBXXBX, XBXXBBBX, XBBXBX, or XBXBBX. Applicants hereby elect, with traverse, XBBBXXBX, for the reasons outlined below.

The Examiner alleges at page 2 of the Office Action that the inventions are distinct from one another because the methods of Groups II-V differ in the method objectives, method steps and parameters and in the reagents used. At page 3 of the Office Action, it is alleged that the invention of Group I is related to the inventions of Groups II-V as product and processes of use.

The Examiner alleges at page 3 of the Office Action that each of the four peptide groups comprises structurally and functionally diverse products. The Examiner further alleges that the examination of all structures would require different searches of the U.S. Patent and scientific literature, and would require the consideration of different patentability issues. In addition, the Examiner asserts that searches required for the peptide groups would not be co-extensive. Applicants respectfully disagree.

Restriction is proper only if the pending claims represent independent or distinct inventions, *and* there is a serious burden in searching and examining the entire application. MPEP §803. Here, Examiner cannot show that Groups I-V represent independent or distinct inventions and that there is a serious burden on searching and examining these claim groups in one application. In addition, there is no serious burden in searching the claimed consensus peptides of the invention, regardless of whether the four peptide consensus

sequences are independent or distinct. Thus, to the extent discussed below, the restriction requirement is improper and should be withdrawn.

Restriction of Groups I to V is Not Proper

According to MPEP 802,

“The term “distinct” means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, . . . “

Contrary to the Examiner’s assertion, the subject matter of the claims is not capable of separate manufacture, use or sale. All of the claims of Groups II-V require the presence or use of the peptides of Group I or depend from such a claim. Thus, restriction is not proper as the groups are not distinct.

In addition, there is no serious burden in searching the claimed invention, regardless of whether the claim groups are independent or distinct. As Examiner has stated, all claim groups have the peptides of Group I in common. Indeed, at page 3 the Examiner asserts that Groups II-V relate to methods of using the peptides of Group I. It is USPTO practice to direct a patentability search to a compound itself, even if the claims are directed to a method of using the compound. Here, the most efficient way to search the present claims would be to concentrate on the peptides of Group I. Such a search would undoubtedly reveal methods of using the peptides. Indeed, a search of the methods of Groups II-V that is not focussed on the Group I peptides would itself be overly broad and burdensome. In addition, Applicants note that Examiner has classified the groups similarly, though not identically. Groups I and II are each classified in class 530, while Groups III, IV, and V are all classified in class 514, subclass 2.

Because a search of the peptides of Group I would encompass the methods of use in Groups II-V, Applicants believe there is no serious burden in searching and examining Groups I-V in the same application. It is unlikely that a search of one claim group would reveal no art that is pertinent to the others. Applicants therefore respectfully request reconsideration and withdrawal of the restriction requirement with respect to Groups I, II, III, IV, and V.

Claim Groups II, III, IV, and V Are Not Distinct

Applicants further submit that Groups II, III, IV, and V should not be restricted into four groups and request that these four groups be combined into one. The discussion above with respect to searching the peptides of Group I in all claim groups applies equally here.

Inventions are distinct only if they are 1) classified separately, 2) have acquired separate status in the art when classified together, or 3) require a different field of search (i.e., it is necessary to search for one invention in places where no pertinent art exists for the others). MPEP § 808.02.

With regard to Groups III-V, the groups are not classified separately under §808.02(A), as Examiner has put each group in the identical class (514). Moreover, these groups are classified in subclass 2. In addition, Group II is also a method of use of the peptides of Group I, and although not classified identically to Groups III-V, it is classified similarly.

Groups II-V do not represent “separate inventive effort” under §808.02(B), as they all relate to basic methods for using the claimed peptides based on the biological activity and function of the peptides.

Finally, Groups III-V do not require a different field of search under §808.02(C), because they have the identical classification and subclassification, while Group II is classified in a similar class. Applicant also notes that in performing a patentability search for use of the peptides of the invention, the Examiner will necessarily uncover the prior art pertaining to the claims of Groups II-V, because all relate to methods of use of the same peptides. Therefore, no undue burden is placed on the Examiner to search for methods of use of the peptides in Groups II-V and it is unlikely that a search of one claim group would reveal no art that is pertinent to the other.

Therefore, Groups II, III, IV, and V fail to satisfy any of the criteria set forth in MPEP §808.02, and are not distinct.

The Examiner has provided no reasoning why Groups II-V represent distinct inventions, but has merely stated a conclusion that the inventions are distinct. Such a conclusory statement is inadequate to establish that the claim groups represent distinct inventions. MPEP §§ 808.02(B) and 816. The present restriction requirement is therefore improper, and should be withdrawn.

Species Restriction of Peptide Groups is Improper

Applicants respectfully submit that the election of species requirement is improper because the peptide groups are directed to related subject matter and are similar in structure and function. Furthermore, all peptide groups are classified in class 530 and subclass 300. All four peptides or consensus sequences are synthetic peptides of six or eight residues with a high affinity for glycosaminoglycan and proteoglycans, and B is arginine or lysine or a combination of arginine and lysine for each of the four peptides/consensus sequences. The application as filed shows that peptides comprised of tandem repeats of the sequences XBBBXXBX, XBXXBBBX, XBBXBX, and XBXBBX, having similar molecular weights, bind heparin and proteoglycans with similar affinities, and exhibit similar heparin neutralization activities *in vivo* (see Tables I, II, and III).

Moreover, the application provides that the directionality of the sequences does not matter, i.e., they are just as active when tested in their reverse orientations. For example, the heparin binding affinity of (ARKKAACA)₃, representative of consensus sequence XBBBXXBX, is about 135 nM, while that of the reverse sequence (AKAACKRA)₃, representative of consensus sequence XBXXBBBX, is about 132 nM (Table II). In addition, the six-mer tandem repeat (AKKARA)₄, representative of consensus sequence XBBXBX, has a similar molecular weight (M_r 2520) and dissociation constant (174 nM) to the tandem repeat eight-mers mentioned above (Table II).

Applicants also believe that in performing a patentability search in the context of the consensus sequences of the invention, the Examiner will necessarily uncover art pertaining to any such sequence. Thus, no undue burden is placed upon the Examiner to search for all four peptides/consensus sequences at the same time.

Conclusion

Applicants respectfully submit that Groups I, II, III, IV, and V are not distinct. Furthermore, because a single search for the peptide groups of claim Group I would necessarily uncover prior art relevant to claim Groups II, III, IV, and V, no undue search burden is placed on the Examiner. For these reasons, Applicants respectfully request withdrawal of the restriction requirement with respect to Groups I, II, III, IV, and V.

Applicants respectfully submit that the consensus sequences are not distinct. Also, a single search would necessarily uncover prior art on all four consensus sequences of synthetic peptides of the invention, and no undue search burden is placed on the Examiner. For these reasons, Applicants respectfully request withdrawal of the election requirement with respect to XBBBXXBX, XBXXBBBX, XBBXBX, or XBXBBX.

Applicants believe this response to be fully responsive to the outstanding Restriction Requirement and request prosecution on the merits.

Respectfully submitted,

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